IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT
STATE OF FLORIDA, IN AND FOR PASCO COUNTY
CIVIL DIVISION

NANCY ANDERSON,

Plaintiff,

v.

Case No: 51-07-CA-4086-ES

Division: Y

BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE, a Florida Corporation; MOUHANNAD BUDEIR, D.D.S.; FARDIN ZARE, D.D.S.; THEODORE KIELTS, D.D.S.; and MERCK & CO., INC.;

Defendants.
_____/

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, NANCY ANDERSON, by and through their undersigned legal counsel, hereby sues Defendants BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE, MOUHANNAD BUDEIR, D.D.S., FARDIN ZARE, D.D.S., THEODORE KIELTS, D.D.S., and MERCK & CO., INC. and allege as follows:

JURISDICTION AND VENUE

1. This is an action for damages in excess of $15,000.00, exclusive of costs.

PARTIES

2. Plaintiff NANCY ANDERSON was born August 7, 1934. At all relevant times, Plaintiff was a resident of Pasco County, Florida.

3. At all times material hereto, Defendant, BRITE DENTAL CORPORATION, was a corporation duly organized and licensed to do business in the State of Florida. BRITE DENTAL CORPORATION owned and operated a dental

practice d/b/a CREATIVE DENTAL CARE (hereinafter sometimes referred to as "CREATIVE DENTAL"), located at 5046 Mission Square Circle, Zephyrhills, Florida 33542.

4. At all times material hereto, MOUHANNAD BUDEIR, D.D.S. (hereinafter sometimes referred to as "BUDEIR") was a dentist licensed to practice as a healthcare professional in the State of Florida and owned and/or was employed by CREATIVE DENTAL CARE. BUDEIR held himself out as a specialist in the field of dentistry.

5. At all times material hereto, FARDIN ZARE, D.D.S. (hereinafter sometimes referred to as "ZARE") was a dentist licensed to practice as a healthcare professional in the State of Florida and owned and/or was employed by CREATIVE DENTAL CARE. ZARE held himself out as a specialist in the field of dentistry.

6. At all times material hereto, THEODORE KIELTS, D.D.S. (hereinafter sometimes referred to as "KIELTS") was a dentist licensed to practice as a healthcare professional in the State of Florida and was employed by CREATIVE DENTAL CARE. KIELTS held himself out as a specialist in the field of dentistry.

7. At all times material hereto, MERCK & CO., INC., (hereinafter sometimes referred to as "MERCK"), was a Foreign Corporation licensed to do business in the State of Florida with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey.

8. At all times material hereto, Defendant Merck, through its agents, servants, employees, and apparent agents was the designer, manufacturer, marketer,

distributor, and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

9. Defendant Merck, either directly or through its agents, apparent agents, servants, or employees, at all relevant times, sold and distributed FOSAMAX in Pasco County and the State of Florida.

10. Defendant Merck derives substantial revenue from pharmaceutical products used or consumed in Pasco County and the State of Florida.

11. Defendant Merck expected, or should have expected, that its business activities could or would have consequences within Pasco County and the State of Florida.

12. Venue is proper in Pasco County, Florida.

SUMMARY OF THE CASE

13. From 2003 through September 24, 2004, Plaintiff Nancy Anderson was provided routine dental care at Creative Dental Care.

14. On or about October 15, 2004, Plaintiff Nancy Anderson presented at Creative Dental for preparation of tooth #29 for a crown.

15. During the preparation being performed by Defendant Budeir, the tooth broke off at the gum line.

16. Dr. Budeir placed the Plaintiff on Clindamycin 300 mg 40 tablets and made a follow-up appointment for removal of the tooth.

17. On or about October 19, 2004, Plaintiff returned to Creative Dental and Defendant Budeir extracted tooth #29 under local anesthesia. Defendant Budeir prescribed Codeine for pain.

18. On or about November 8, 2004, Plaintiff called Creative Dental and stated that she still had pain in the area where the tooth had been removed.

19. On or about November 9, 2004, Plaintiff Nancy Anderson was examined at the office of Creative Dental by Dr. Budeir. She had pain in the area of the extraction. Defendant Budeir recommended fixing a bridge from tooth #20 to #30 and removing the existing crown.

20. On or about November 17, 2004, Defendant Budeir called in a prescription for Clindamycin 150mg, 10 tablets to be taken prior to next procedure.

21. On or about December 16, 2004, Plaintiff called the office stating her belief that tooth extraction area was infected and was told to come in for an exam.

22. Later on or about December 16, 2004, Plaintiff was examined by Defendant Fardin Zare, D.D.S. Defendant Zare prescribed Clindamycin 150mg, indicating he felt there was an infection present.

23. On or about December 22, 2004, Plaintiff was again examined by Defendant Budeir to whom she told she could feel her bone with her tongue. There was still swelling on the buccal surface of the gum in the area of tooth #s 26 and 27. Budeir stated he wanted to see Plaintiff back in one week and to bring her plate with her.

24. On or about December 28, 2004, Plaintiff returned to Creative Dental, at which time Defendant Budeir adjusted the plate. Budeir noted a sore mound under her chin. Budeir prescribed Erythromycin 500 mg 3 times per day. Budeir recommended that Plaintiff see a medical doctor in one week if the area was still sore.

25. On or about January 5, 2005, Plaintiff called in to Creative Dental to report that her pain was no better. She complained of a pus pocket in the area of the

extraction and constant throbbing. Defendant Budeir recommended a second opinion with Dr. Theodore Kielts.

26. On or about January 6, 2005, Plaintiff was examined by Dr. Theodore Kielts. It is noted in Plaintiff's medical records that Defendant Kielts felt there was a resolving abscess and ordered another round of Clindamycin 150 mg for 10 days.

27. On or about January 11, 2005, Plaintiff returned to Creative Dental, at which time she was still on antibiotics and still had a knot in her jaw. Budeir recommended that she finish the antibiotics and return in one week.

28. On or about January 19, 2005 and February 2, 2005, Dr. Budeir again examined Ms. Anderson. During both visits she still complained of infection, severe pain, and swelling in her jaw. In the record it was noted that pus was oozing out in the area of tooth #s 21 and 22. The notes reflect that Ms. Anderson was to see an infectious disease specialist on Friday. Budeir wrote another prescription for Clindamycin 21 tablets.

29. On or about February 4, 2005, Plaintiff was examined by Keith Rosenbach, M.D. from the Infectious Disease Division of Florida Medical Clinic. Dr. Rosenbach stated that the patient needed intravenous antibiotics.

30. On or about February 11, 2005, Plaintiff was admitted to Pasco Regional Medical Center with a primary diagnosis of osteomyelitis of the mandible.

31. During her stay at Pasco Regional Medical Center, Plaintiff was seen by various disciplines, the consensus being that she had had osteomyelitis of the mandible. Because there was no oral surgeon on staff, Ms. Anderson was transferred to University Community Hospital ("UCH") for further treatment, including surgery.

32. On or about February 16, 2005, Barry Levine, D.M.D., performed an aggressive debridement and biopsies of the mandible. He noted in Plaintiff's records that there were marked areas of necrotic and ischemic bone next to the premolars, marked granulation tissue present, as well as ischemic and necrotic tissue. Dr. Levine determined that Ms. Anderson had a pathological fracture of her anterior mandible, which was totally ischemic. Erich arch bars were applied and a maxillary fixation was performed. Cultures were taken.

33. On or about February 28, 2005, Dr. Levine performed another surgical procedure wherein he re-applied the arch bars with steel wire and the infected area was again biopsied. The pathology reports showed osteomyelitis, with acute and chronic inflammation. Ms. Anderson also suffered from osteonecrosis of the jaw.

FOSAMAX FACTS

34. From on or about May of 1996, until the present, the Plaintiff was prescribed FOSAMAX for its intended purpose of combating or treating osteoporosis.

35. At all relevant times Defendant MERCK was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

36. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant MERCK as FOSAMAX.

37. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's

disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

38. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.

39. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, MERCK knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

40. MERCK knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, MERCK knew or should have known that Bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patient's mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

41. MERCK also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of the bone marrow).

42. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

43. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

44. Shortly after Defendant MERCK began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant MERCK failed to implement further study of risk of osteonecrosis of the jaw relative to FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

45. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

46. Since FOSAMAX was release, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

47. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and

alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

48. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

49. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

50. Rather than warn patients, and despite knowledge known by Defendant about increase risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continue to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

51. FOSAMAX is one of MERCK'S top selling drugs, averaging more than $3 billion a year in sales.

52. Consumers, including Plaintiff Nancy Anderson, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the condition.

53. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant MERCK did not adequately and

sufficiently warn consumers, including Plaintiff Nancy Anderson, or the medical community, of such risks.

54. As a direct result, Plaintiff Nancy Anderson was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff Nancy Anderson requires and will in the future require ongoing medical care and treatment.

55. Plaintiff Nancy Anderson has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

56. Plaintiff Nancy Anderson was prescribed and began taking FOSAMAX in or about May 1996.

57. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

58. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe osteonecrosis of the jaw and osteomyelitis.

59. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injury and emotional distress.

60. Plaintiff used FOSAMAX, which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

61. Plaintiff would not have used FOSAMAX had Defendant MERCK properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

62. Defendant MERCK, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

63. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of MERCK'S acts, omissions, and misrepresentation.

MEDICAL NEGLIGENCE FACTS

64. At all times material hereto, CREATIVE DENTAL, through its agents and employees, had a duty or assumed a duty or responsibility to diagnose, treat and monitor NANCY ANDERSON throughout the treatment of her condition. These duties included, but were not limited to, the following actions:

a) determine what medication she was taking;

b) diagnose her problem and properly treat her condition in a timely fashion namely her infection in anterior mandible;

c) refer Ms. Anderson to a higher level of care after it was clear the infection was not being eradicated by continual use of the antibiotic, Clindamycin;

d) vicariously liable for the negligence of Drs. Budeir, Zare and Kielts.

65. Defendant Mouhannad Budeir, D.D.S., as the dentist performing the initial dental work and ultimately responsible for Ms. Anderson's care, had a duty or assumed a duty or responsibility to properly diagnose, treat and monitor NANCY ANDERSON. These duties included, but were not limited to the following:

a) timely diagnose and treat infection following extraction of tooth in an appropriate manner to include cultures and sensitivities of the bacteria and choice of appropriate antibiotic;

b) diagnose and treat infection that presented in NANCY ANDERSON'S anterior mandible;

c) refer NANCY ANDERSON to a higher level of care after it was clear the infection was not being eradicated by continual use of the single antibiotic, Clindamycin;

66. Defendant FARDIN ZARE, D.D.S., as a dentist examining NANCY ANDESON at Creative Dental during the time she was being treated for this problem and ultimately responsible for Ms. Anderson's care, had a duty or assumed a duty or responsibility to properly diagnose, treat and monitor NANCY ANDERSON. These duties included, but were not limited to the following:

a) timely diagnose and treat infection following extraction of tooth in an appropriate manner to include cultures and sensitivities of the bacteria and choice of appropriate antibiotic;

b) diagnose and treat infection that presented in NANCY ANDERSON'S anterior mandible;

c) refer NANCY ANDERSON to a higher level of care after it was clear the infection was not being eradicated by continual use of the single antibiotic, Clindamycin;

67. Defendant Theodore Kielts, D.D.S., as a dentist examining NANCY ANDESON at Creative Dental during the time she was being treated for this problem and ultimately responsible for Ms. Anderson's care, had a duty or assumed a duty or responsibility to properly diagnose, treat and monitor NANCY ANDERSON. These duties included, but were not limited to the following:

a) timely diagnose and treat infection following extraction of tooth in an appropriate manner to include cultures and sensitivities of the bacteria and choice of appropriate antibiotic;

b) diagnose and treat infection that presented in NANCY ANDERSON'S anterior mandible;

c) refer NANCY ANDERSON to a higher level of care after it was clear the infection was not being eradicated by continual use of the single antibiotic, Clindamycin;

68. As a direct and proximate cause of departures or deviations from the accepted standard of care on the part of one or more of the Defendants as particularly described above and in the following counts, Plaintiff Nancy Anderson was caused damages to include osteonecrosis of the jaw, osteomyelitis, pain therefrom, permanent loss of bone, aggravation of a preexisting dental conditions, aggressive debridement surgery, continued antibiotic treatment, future surgical requirements, weight loss, aggravation of other existing medical problems, physical handicap, permanent injury,

mental pain and suffering, and loss of the ability to live a normal life. Plaintiff will continue to suffer these losses in the future.

69. In accordance with Florida Statute §766.106 and/or 766.102, Plaintiff served upon each Defendant, by certified mail, return receipt requested, a Notice of Intent to initiate a claim resulting from medical negligence, sent on or about December 5, 2006.

70. The undersigned counsel, pursuant to Florida Statute §768.495(1), hereby certifies that reasonable investigation in this case has given rise to a good faith belief that grounds exist for an action against the above named Defendants.

COUNT I: CLAIM AGAINST BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE

71. Plaintiff restates the allegations set forth above as if fully rewritten herein.

72. Nancy Anderson's damages were the direct and proximate result of the departure or deviations from the recognized and accepted standard of care on the part of BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE in one or more of the following respects:

a) determine what medication she was taking;

b) diagnose her problem and properly treat her condition in a timely fashion namely her infection in anterior mandible;

c) failed to refer Ms. Anderson to a higher level of care after it was clear the infection was not being eradicated by continual use of the antibiotic, Clindamycin;

d) vicariously liable for the negligence of Drs. Budeir, Zare and Kielts.

73. Defendant BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE is responsible for the acts or omission of its employees.

WHEREFORE, the Plaintiff demands judgment for damages against BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE in excess of $15,000.00, together with costs, and a trial by jury.

COUNT II: CLAIM AGAINST MOUHANNAD BUDEIR, D.D.S.

74. Plaintiff restates the allegations set forth above as if fully rewritten herein.

75. Nancy Anderson's damages were the direct and proximate result of the departure or deviations from the recognized and accepted standard of care on the part of Mouhannad Budeir, D.D.S. in one or more of the following respects:

a) timely diagnose and treat infection following extraction of tooth in an appropriate manner to include cultures and sensitivities of the bacteria and choice of appropriate antibiotic;

b) failed to diagnose and treat infection that presented in NANCY ANDERSON'S anterior mandible;

c) failed to refer NANCY ANDERSON to a higher level of care after it was clear the infection was not being eradicated by continual use of the single antibiotic, Clindamycin.

WHEREFORE, the Plaintiff demands judgment for damages against Defendant MOUHANNAD BUDEIR in excess of $15,000.00, together with costs, and a trial by jury.

COUNT III: CLAIM AGAINST FARDIN ZARE, D.D.S.

76. Plaintiff restates the allegations set forth above as if fully rewritten herein.

77. Nancy Anderson's damages were the direct and proximate result of the departure or deviations from the recognized and accepted standard of care on the part of Fardin Zare, D.D.S. in one or more of the following respects:

a) timely diagnose and treat infection following extraction of tooth in an appropriate manner to include cultures and sensitivities of the bacteria and choice of appropriate antibiotic;

b) failed to diagnose and treat infection that presented in NANCY ANDERSON'S anterior mandible;

c) failed to refer NANCY ANDERSON to a higher level of care after it was clear the infection was not being eradicated by continual use of the single antibiotic, Clindamycin.

WHEREFORE, the Plaintiff demands judgment for damages against Defendant FARDIN ZARE, D.D.S. in excess of $15,000.00, together with costs, and a trial by jury.

COUNT IV: CLAIM AGAINST THEODORE KIELTS, D.D.S.

78. Plaintiff restates the allegations set forth above as if fully rewritten herein.

79. Nancy Anderson's damages were the direct and proximate result of the departure or deviations from the recognized and accepted standard of care on the part of Theodore Kielts, D.D.S. in one or more of the following respects:

a) timely diagnose and treat infection following extraction of tooth in an appropriate manner to include cultures and sensitivities of the bacteria and choice of appropriate antibiotic;

b) failed to diagnose and treat infection that presented in NANCY ANDERSON'S anterior mandible;

c) failed to refer NANCY ANDERSON to a higher level of care after it was clear the infection was not being eradicated by continual use of the single antibiotic, Clindamycin.

WHEREFORE, the Plaintiff demands judgment for damages against Defendant THEODORE KIELTS, D.D.S. in excess of $15,000.00, together with costs, and a trial by jury.

CLAIMS AGAINST DEFENDANT MERCK & CO., INC.

80. Plaintiff restates the allegations set forth above as if fully rewritten herein.

81. Defendant Merck, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other uses.

82. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff Nancy Anderson, have suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw.

83. Defendant concealed and continues to conceal its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff Nancy Anderson, other consumers, and the medical community.

84. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX, which has caused and will continue to cause Plaintiff's various injuries and damages. Plaintiff accordingly seeks compensatory damages.

85. As a result of Defendant's actions and inaction, Plaintiff Nancy Anderson was injured due to her ingestion of FOSAMAX, which has caused and will continue to

cause Plaintiff's various injuries and damages. Plaintiff accordingly seeks compensatory damages.

COUNT V: NEGLIGENCE

86. Plaintiff restates the allegations set forth above as if fully rewritten herein.

87. Defendant owed Plaintiff, Nancy Anderson, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

88. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a) failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b) failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c) failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d) designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e) failing to exercise due care when advertising and promoting FOSAMAX; and

f) negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

89. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Nancy Anderson sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

COUNT VI: STRICT LIABILITY

90. Plaintiff restates the allegations set forth above as if fully rewritten herein.

91. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Nancy Anderson.

92. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

93. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

94. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

95. FOSAMAX was defective in its design or formulation in that is posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

96. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

97. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumer, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

98. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm cause by FOSAMAX.

99. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

100. As a direct and proximate consequence of Defendant's conduct, Plaintiff Nancy Anderson sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT VII: BREACH OF EXPRESS WARRANTY

101. Plaintiff restates the allegations set forth above as if fully rewritten herein.

102. Defendant expressly represented to Plaintiff Nancy Anderson and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

103. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

104. At all relevant times FOSAMAX did not perform as safely as and ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

105. Plaintiff Nancy Anderson, other consumers, and the medical community relied upon Defendant's express warranties.

106. As a direct and proximate result of Defendant's actions, plaintiff Nancy Anderson sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT VIII: BREACH OF IMPLIED WARRANTY

107. Plaintiff restates the allegations set forth above as if fully rewritten herein.

108. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

109. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

110. Defendant was aware that consumers, including Plaintiff Nancy Anderson, would use FOSAMAX for treatment of osteoporosis and for other purposes.

111. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

112. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

113. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

114. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

115. As a direct and proximate result of Defendant's actions, Plaintiff Nancy Anderson sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT IX: FRAUDULENT MISREPRESENTATION

116. Plaintiff restates the allegations set forth above as if fully rewritten herein.

117. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a) Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had

been tested and found to be safe and effective for the treatment of pain and inflammation; and

b) Defendant represented that FOSAMAX was safer than other alternative medications.

118. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

119. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

120. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

121. Plaintiff's doctors, and others relied upon the representations.

122. Defendant's fraudulent representations evidenced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

123. As a direct and proximate result of Defendant's actions, Plaintiff Nancy Anderson sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent

conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT X: FRAUDULENT CONCEALMENT

124. Plaintiff restates the allegations set forth above as if fully rewritten herein.

125. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a) Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b) Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternative available on the market.

126. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

127. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

128. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

129. Plaintiff's doctors and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

130. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff Nancy Anderson sustained osteonecrosis of the jaw and was caused to suffer severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer pain and mental anguish and has incurred, and will continue to incur, expense for medical care and treatment due to the injuries caused by FOSAMAX.

WHEREFORE, the Plaintiff demands judgment for damages against Defendant MERCK in excess of $15,000.00, together with costs, and a trial by jury.

Respectfully submitted,

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